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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KIM, YOUNG J	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/902,941	HENDERSON ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 20-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 20-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action responds the After Final Amendment received on June 15, 2004.

Preliminary Remark

Further consideration of the application necessitates the following new grounds of rejection. Therefore, the finality of the prosecution is hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The Revised Interim Written Description Guidelines can be obtained from: http://uspto.gov/web/menu/written.pdf.

The specification discloses SEQ ID NO: 808 which corresponds to the cDNA encoding the polypeptide of SEQ ID NO: 809. The polypeptide of SEQ ID NO: 809 is disclosed contemplated as being a novel isoform of cancer testis antigen, XAGE-1 (page 165, lines 13-29). SEQ ID NO: 809 meets the written description and enablement provisions of 35 USC 112, first paragraph. However, claims are directed to an isolated polypeptide that is at least 90% homologous to the polypeptide of SEQ ID NO: 809 (instant claim 21) as well as said polypeptide

that binds an antibody specific for a polypeptide of SEQ ID NO: 809 (instant claim 23). The specification provides insufficient written description to support the genus encompassed by the claim because the claims embrace a polypeptide of at least 90% homology of ***any and all function*** to which applicants have not reasonable described.

According to Example 14 of the written description guidelines, a claim drawn to a protein having SEQ ID NO: 3 and variants thereof that are at least 95% identical to SEQ ID NO: 3 ***and catalyzes the reaction of A → B*** is deemed to be described when the specification conveys to a skilled artisan that a functional description of the protein essential to the operation of the claimed invention is recited in the claim. Since the procedure for making variants of SEQ ID NO: 3 are conventional in the art and an assay is described ***which will identify other proteins having the claimed activity***, one skilled in the art would recognize that proteins which comprise the same identity but does not have the recited function would not be embraced by such claim.

The instant situation is, however, not analogous to the above situation because the instant specification evidences that Applicants have not yet identified what the function of the encoded polypeptide is:

"Initial database searches failed to detect any sequence homology with proteins in the database, suggesting that L552S (or polynucleotide of SEQ ID NO: 808) encodes a novel protein (the polypeptide of SEQ ID NO: 809) ***of unknown function***." (page 165, lines 13-15, specification)

Without such functional limitation, one skilled in the art would not be able to conclude that the single species of SEQ ID NO: 809 would be representative of genus of polypeptides of any function having the same degree of homology.

Therefore, with the exception of the polypeptide comprising SEQ ID NO: 809, the skilled artisan cannot envision the detailed chemical structure of the encompassed claimed polypeptide.

Double Patenting – 35 U.S.C. 101

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The ***filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.***

Claim 20 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 6,630,574 B1. This is a double patenting rejection.

Claim 20 of the instant application is drawn to an isolated polypeptide comprising an amino acid sequence of SEQ ID NO: 809.

The instant specification discloses that the polypeptide of SEQ ID NO: 809 is a full-length amino acid sequence of L552S, encoded by the full-length cDNA of SEQ ID NO: 808 (page 38, lines 8-9).

Claim 1 of the '574 patent is drawn to an isolated polypeptide comprising the amino acid sequence encoded by polynucleotide of SEQ ID NO: 808.

The specification of the '574 patent discloses that SEQ ID NO: 808 is a full-length cDNA of L552S which encodes the polypeptide of SEQ ID NO: 809, a full-length amino acid sequences of L552S (column 31, lines 1-4).

A sequence homology search (attached hereto) reveals that the polypeptides of SEQ ID NO: 809 of the instant application and the '574 patent are identical (100% homology).

Since polypeptide encoded by the polynucleotide of SEQ ID NO: 808 (claim 1 of the '574 patent) encodes the same polypeptide as that which is claimed in claim 20 of the instant application, as evidenced above, statutory double patenting is proper.

Cancellation of the claim is required.

Double Patenting – Nonstatutory ODP

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,630,574. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 21-25 are drawn to an isolated polypeptide that has at least 90% identity to the polypeptide of SEQ ID NO: 809; an isolated polypeptide comprising at least 10 consecutive

amino acid residue of the polypeptide of SEQ ID NO: 809; or an isolated polypeptide comprising an immunogenic portion selected from SEQ ID NO: 809.

Claim 1 of the '574 patent discloses a polypeptide that comprises SEQ ID NO: 809. The specification discloses that antibodies specific for the antigen (polypeptide of SEQ ID NO: 809), "were shown to be present in effusion or sera of lung cancer patients but not in normal donors," (page 185, lines 10-13).

Therefore, based on such disclosure a polypeptide comprising a recited degree of homology to or an immunogenic portion along the stretch of the disclosed polypeptide of SEQ ID NO: 809 is considered to be obvious to one of ordinarily skilled in the art of immunology, rendering the instant claims obvious.

For the above reasons, the invention as claimed is obvious over claims 1-2 of the '574 patent.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)

(see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (517) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0507.

Young J. Kim
Patent Examiner
Art Unit 1637
6/24/04

yjk